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TITLE: A Randomized, Placebo-Controlled Trial of D-Cycloserine for the Enhancement of Social Skills Training in Pervasive Developmental Disorders

PRINCIPAL INVESTIGATOR: Dr. Marjorie McCaskey

CONTRACTING ORGANIZATION: Indiana University Health
Indianapolis, IN 46202

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Dr. Marjorie McCaskey
mmccaske@iuhealth.org

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ABSTRACT

The main objective of this application is to determine whether D-cycloserine (DCS) can enhance the efficacy of social skills training (SST) in the treatment of children and young adolescents with autism spectrum disorders (ASDs). We will evaluate the efficacy, tolerability, and last effects of DCS given one hour prior to each of 10 weekly SST sessions for the treatment of social impairment in 68 children and young adolescents (ages 5-11 years) with ASDs during a randomized placebo-controlled trial. The safety and tolerability of DCS and durability of treatment response will also be examined.

In 2011, IRB approval received to allow for enrollment of youth with 1) stable seizure disorders and 2) up to two concomitant psychotropic non-glutamatergic drugs. Approval also received for the addition of the Autism Diagnostic Observation Schedule (ADOS) to better characterize ASD pathology.

In 2012, the study was expanded to include a second site, led by former Indiana University site PI Craig Erickson, at Cincinnati Children's Hospital Medical Center. This expansion increased the overall study N to 68 youth with ASD and 34 neurotypical peers (originally 52 youth with ASD and 26 neurotypical peers at Indiana University only). Dr. Noha Minshawi was also named lead PI at the Indiana University Site at that time. In addition, IRB approval received to 1) complete TRIAD Social Skills Assessment (TSSA) and Eye Tracking with typically developing peers to provide a normative sample, and 2) record Play Coding behaviors of the typically developing peers from the Social Skills Training sessions.

INTRODUCTION

The long-range goal of this research is to identify better treatments for the core social and communication impairment of autism spectrum disorders (ASDs). The main objective of this application is to determine whether D-cycloserine (DCS) can enhance the efficacy of social skills training (SST) in the treatment of children and young adolescents with ASDs. The central hypothesis is that DCS will enhance the learning of social skills over the course of 10 weeks of SST. To test this hypothesis, we will evaluate the efficacy of DCS given one hour prior to each of 10 weekly SST sessions for the treatment of social impairment in 68 children and young adolescents (ages 5-11 years) with ASDs during a randomized placebo-controlled trial. The safety and tolerability of DCS and durability of treatment response will also be examined.

BODY

- August 5, 2009 - Final IRB approval was obtained.
- December 25, 2009 – IRB approved an amendment containing initial revisions requested by the Department of Defense Human Research Protections Office (HRPO).
- February 4, 2010 - IRB approved an amendment containing final revisions requested by the HRPO.
- March 1, 2010 – Enrollment began at IU.
- March 1 – December 31, 2010 – Two SST groups conducted with a total of 8 children with ASD and 4 typically developing peers at IU.
- January 1 – December 31, 2011 – Four SST groups conducted with a total of 16 children with ASD and 8 typically developing peers at IU.

- January 1 – December 31, 2012 - Four SST groups conducted with a total of 16 children with ASD and 8 typically developing peers at IU.

KEY RESEARCH ACCOMPLISHMENTS

- January 1 - December 31, 2013 - Three SST groups conducted with a total of 12 children with ASD and 6 typically developing peers at IU.
- Enrollment is complete. A total of 13 SST groups have been completed with 52 children with ASD and 26 children with neurotypical development at the Indiana University site. A total of 4 SST groups have been completed with 16 children with ASD and 8 children with neurotypical development at the Cincinnati Children's Hospital Medical Center site.
- All follow up visits and data collection were completed in January 2014 at IU.
- Beginning discussions with biostatisticians to develop data analysis plan.

REPORTABLE OUTCOMES

A no-cost extension has been awarded, allowing each site to focus on quality assurance procedures as we move into data analysis. Reportable outcomes will be available within the next year.

CONCLUSION

The results will be analyzed within the next year after quality assurance and data cleaning procedures have been completed.

REFERENCES:

None.

APPENDICES:

None.

SUPPORTING DATA:

None.